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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT

PAPER NUMBER

3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/792,031	Applicant(s) KENNEDY ET AL.	
	Examiner SHEFALI D. PATEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/24/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. In the reply, filed on October 24, 2008, Applicant amended claims 1 and 12-16.
2. Examiner objected to claims 12 and 15 for minor informalities. Applicant amended claims 12 and 15 to overcome the informalities. Objections are withdrawn.
3. Examiner rejected claim 12 under 35 USC 112, 2nd paragraph, with respect to insufficient antecedent basis concerning conflicting limitations between claim 8 and claim 9. Applicant directed Examiner to paragraph [0062] of the specification in which claims 8 and 12 are described. Rejection is withdrawn.
4. Currently, claims 1-25 are under examination.

Response to Arguments

5. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection, as Applicant amended independent claim 1 with subject matter not previously in the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1, 7-10, 12, 19, 21-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki (US 5,318,535), and further in view of Goodin (US 5,425,712).

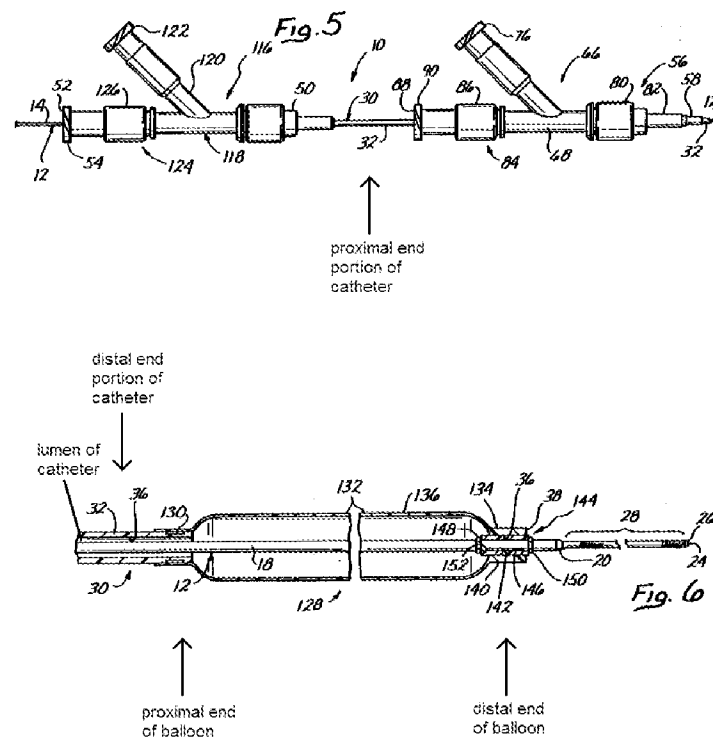
In regards to claim 1, Miraki teaches a balloon catheter (Figures 5-7, balloon catheter [10]) comprising:

- a. a inflatable balloon (balloon [132]) comprising a balloon wall (side wall [136]) defining an interior volume, the balloon further comprising a distal end, a proximal end (*labeled in Figure 6 below*), and a central portion disposed therebetween
- b. a catheter (shaft [32]) comprising a distal end portion (*labeled in Figure 6 below*) and a proximal end portion (*labeled in Figure 5 below*), the proximal end portion comprising a connector (Y-connector [118]) configured to engage an inflation device (column 8, lines 50-56), the distal end portion fixedly connected to the proximal end of the balloon due to bond [130] (column 8, line 68 to column 9, lines 1-2), and a lumen (*labeled in Figure 6 below*) extending through the catheter along an axis thereof and in fluid communication with the interior volume of the balloon via bore [36][36'] (column 9, lines 12-16)
- c. a stiffening member (guide wire assembly [12]) extending distally from the distal end portion of the catheter and through the interior volume of the balloon, the stiffening member being non-fixedly connected to the distal end of the balloon via the releasable engagement of collar [146] of stiffening member [12] and seal section [134] of balloon [132] (column 9, lines 2-4)(column 9, lines 25-32),

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- d. wherein movement of the distal end of the balloon relative to the proximal end of the balloon is not restrained by the catheter, *since the proximal end of the balloon is the only portion of the balloon that is attached to the catheter*
- e. wherein axial movement of the distal end of the balloon relative to the proximal end of the balloon in a direction generally parallel to the axis of the catheter is not restrained by the stiffening member, *since the stiffening member [12] is non-fixedly connected to the distal end of the balloon* (column 9, lines 2-4)(column 9, lines 25-32)
- f. wherein transverse movement of the distal end of the balloon relative to the proximal end of the balloon in a direction generally perpendicular to the axis of the catheter is continuously restrained by the stiffening member, *since the presence of the stiffening member within the interior volume of the balloon prevents the balloon wall from completely moving inwards in the transverse direction upon deflation (Figure 7).*

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Miraki does not teach that the stiffening member [12] is fixedly and non-removably connected to the catheter [32] at one or more locations (Figures 6-7). Goodin teaches a balloon catheter (Figures 1-2, balloon dilatation catheter [10]) with a stiffening member (inner tube [21]) that is fixedly and non-removably connected to a catheter (outer tube [31]) at one or more locations (column 3, lines 6-8). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the stiffening member, of the catheter of Miraki, to be fixedly and non-removably connected to the catheter, as taught by Goodin, as fixing the stiffening member with respect to the catheter will increase the rigidity of the proximal end of the balloon catheter, thereby providing additional support to the proximal end of the balloon catheter (Figure 1) (column 3, lines 6-8).

In regards to claim 7, in a modified catheter of Miraki and Goodin, Miraki teaches that the stiffening member [12] comprises a proximal portion (proximal end portion [14]) extending along and generally parallel to the axis of the catheter [32] (Figure 5).

In regards to claim 8, in a modified catheter of Miraki and Goodin, Miraki teaches that the proximal portion [14] of the stiffening member [12] is disposed within the lumen of the catheter [32] (Figure 5); however, Miraki does not teach that the proximal end of the proximal portion of the stiffening member is fixedly connected to the proximal end portion of the catheter (Figure 6 to Figure 7). Goodin teaches that the proximal end of the proximal portion of the stiffening member [21] is fixedly connected to the proximal end portion of the catheter [31] (column 3, lines 6-8). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the proximal end of the stiffening member, of the modified catheter of Miraki and Goodin, to be fixedly connected to the proximal end of the catheter, as taught by Goodin, as fixing the stiffening member with respect to the catheter will increase the rigidity of the proximal end of the balloon catheter, thereby providing additional support to the proximal end of the balloon catheter (Figure 1) (column 3, lines 6-8).

In regards to claim 9, in a modified catheter of Miraki and Goodin, Miraki indirectly teaches that the lumen of the catheter [32] has a first cross-sectional area and the stiffening member [12] has a second cross-sectional area, the second cross-sectional area being less than the first cross-sectional area, since the stiffening member is positioned within the catheter (Figures 5-7). The positioning of the stiffening member with respect to the catheter permits an inflation fluid to flow through the lumen between

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the connector [118] on the proximal end portion of the catheter and the interior volume of the balloon [132] (column 8, lines 50-56)(column 10, lines 53-60).

In regards to claim 10, in a modified catheter of Miraki and Goodin, Miraki teaches that the distal end portion of the catheter [32] comprises a distal end that terminates within the interior volume of the balloon, the distal end comprising a port (bore [36]) to permit the inflation fluid to flow between the lumen of the catheter and the interior volume of the balloon [132] (Figure 6).

In regards to claim 12, in a modified catheter of Miraki and Goodin, Miraki teaches that the distal end portion of the catheter [32] comprises a distal end that terminates within the interior volume of the balloon [132] (Figure 6), the distal end being in sliding engagement (Figure 6 to Figure 7) with the stiffening member [12] so as to align the stiffening member with the axis of the catheter and naturally prevent significant transverse movement of the stiffening member in a direction generally perpendicular to the axis of the catheter due to the closeness of the stiffening member to the inner wall of the catheter in the "distal end portion of catheter" labeled above in Figure 6.

In regards to claim 19, in a modified catheter of Miraki and Goodin, Miraki inherently teaches that an inflation device is connected to the connector [118] on the proximal end portion of the catheter with the statement that "a treatment fluid [is allowed] ... to be introduced via the luer fitting [122] of Y-connector [118] (column 10, lines 55-60).

In regards to claim 21, in a modified catheter of Miraki and Goodin, Miraki teaches that the stiffening member (wire-like shaft [18] of guide wire assembly [12])

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comprises a solid wire having a circular cross-section, as can be seen in Figures 6-7 (column 6, lines 6-9).

In regards to claim 22, in a modified catheter of Miraki and Goodin, Miraki does not teach that the stiffening member comprises a lumen. Goodin teaches a stiffening member (inner tube [22]) that has a guidewire lumen extending therethrough (Figures 1-2) (column 2, lines 47-50). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the stiffening member, of the modified catheter of Miraki and Goodin, with a lumen, as taught by Goodin, as such will allow for the proper placement of a catheter within a blood vessel based on the initial positioning of a guidewire within the blood vessel at the treatment site (column 1, lines 14-20).

In regards to claims 23 and 25, in a modified catheter of Miraki and Goodin, Miraki teaches that the stiffening member [12] has a tapered cross-section at its tapered portion [28], distal to its wire-like shaft portion [18], which has a larger outer diameter than the tapered portion [28] (Figure 6). Therefore, the stiffening member [12] has a first physical property (*outer diameter*) at a first location (*wire-like shaft portion [18]*) and a second physical property (*outer diameter*) at a second location (*tapered portion [28]*), wherein the two physical properties are different since the outer diameter of the portion [18] is larger than the outer diameter of the portion [28].

8. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki and Goodin, as applied to claim 1 above, and further in view of Mulder (US 5,700,242).

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In regards to claims 2-4, in a modified catheter of Miraki and Goodin, Miraki is silent about the balloon's axial length being different in the three following states: deflated state, fully inflated state, and partially inflated state. Mulder teaches a balloon catheter with a balloon that is shortened longitudinally, in the axial direction, when it is inflated (column 2, lines 42-51). Therefore, as the balloon is inflated, the axial length decreases, which means that the deflated axial length, the partially inflated axial length, and the fully inflated axial length would all be different. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the teachings of Mulder to the modified catheter, of Miraki and Goodin, in order to facilitate greater radial expansion of the balloon, without deflecting the tip of the balloon catheter, as the axial length of the balloon decreases with inflation of the balloon (column 2, lines 39-44).

In regards to claim 5, in a modified catheter of Miraki and Goodin, Miraki is silent about the material comprising the balloon wall. Mulder teaches that the balloon is made of an inelastic material (column 2, line 28). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the balloon material of Mulder to the balloon, of the modified catheter of Miraki and Goodin, because Mulder divulges that the use of their material allows for the calculation of the maximum radial diameter that the balloon can inflate to, as further inflation past this maximum radial diameter can cause buckling of the inner catheter shaft, which would deflect the tip of the balloon catheter (column 2, lines 27-37).

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9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki and Goodin, as applied to claim 1 above, and further in view of Weber et al (US 2003/0130716).

In regards to claim 6, in a modified catheter of Miraki and Goodin, Miraki teaches that the balloon [132] is folded and over wrapped on itself in the deflated condition (column 9, lines 5-8); however, Miraki is silent about whether said folding involves axially oriented creases or pleats to facilitate the radial compression of the balloon to the deflated condition. Weber et al teaches that it is common practice in the art to form a number of axially oriented wings in the wall of a balloon and fold the wings down along the side of the balloon (page 2, paragraph [0011]; Figure 2, longitudinal wings [6]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the axially oriented creases or pleats, taught by Weber et al, to the balloon, of the modified catheter of Miraki and Goodin, because Weber et al teaches that such folding of the creases or pleats helps to minimize the diameter of the deflated balloon (page 2, paragraph [0011]).

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki and Goodin, as applied to claim 9 above, and further in view of Hamilton et al (US 6,514,228).

In regards to claim 11, in a modified catheter of Miraki and Goodin, Miraki teaches that the distal end portion of the catheter [32] comprises a distal end that terminates within the interior volume of the balloon; however, Miraki does not teach that said distal end is fixedly connected to the stiffening member, since the stiffening member

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is slidable within the catheter (Figure 6 to Figure 7). Hamilton et al teaches a balloon catheter (Figure 4, balloon catheter [40]) in which a transition tube [46] sealingly connects the distal end of a catheter (shaft [42]) to a stiffening member (tip tube [44]) (column 5, lines 55-57). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the teachings of Hamilton et al to the modified catheter, of Miraki and Goodin, by providing a transition tube between the distal end of the catheter and the stiffening member, as the transition tube provides a fluid connection between the distal end of the catheter and the stiffening member (column 5, lines 52-55).

11. Claims 13, 14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki and Goodin, as applied to claim 1 above, and further in view of Lombardo (US 6,488,653).

In regards to claims 13, 14, and 18, in a modified catheter of Miraki and Goodin, Miraki teaches that the distal end of the balloon [132] comprises a sleeve (cylindrical seal section [134]), a distal end of the stiffening member [12] being slidably disposed within the sleeve (Figure 6 to Figure 7). Miraki does not teach that the sleeve [134] encloses the stiffening member [12], as the sleeve has an open distal end (Figures 6-7). Lombardo teaches a balloon catheter (Figure 1, dilation balloon catheter [10]), wherein a distal end of a balloon (balloon [11]) comprises a sleeve/end cap (distal portion [14]) and a stiffening member (wire guide [13]) is enclosed by the sleeve (Figure 1). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the sleeve, of the modified catheter of Miraki and Goodin, to enclose the

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stiffening member, as taught by Lombardo, as the enclosing sleeve facilitates cannulation of a stricture for placement of the balloon (column 3, lines 11-13).

12. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki, Goodin, and Lombardo, as applied to claim 14 above, and further in view of Chee et al (US 6,315,757).

In regards to claim 15, in a modified catheter of Miraki, Goodin, and Lombardo, Miraki teaches that the sleeve [134] comprises a cannula (collar [146]) disposed therein, the cannula having an interior surface defining a passageway with a cross-sectional area that is less than an interior cross-sectional area of the sleeve (Figures 6-7); however, Miraki does not teach that the interior surface of the passageway of the cannula is configured to slidingly engage an exterior surface of the stiffening member [12], since the cannula is fixed to the stiffening member (Figures 6-7). Chee et al teaches a balloon catheter (Figure 4), wherein a sleeve comprises a cannula (valve seat [210]) disposed therein, the cannula having an interior surface defining a passageway with a cross-sectional area that is less than an interior cross-sectional area of the sleeve, the interior surface of the passageway of the cannula configured to slidingly engage an exterior surface of a stiffening member (guide wire or core wire, not shown). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the cannula, of the modified catheter of Miraki, Goodin, and Lombardo, to slidingly engage an exterior surface of the stiffening member, as taught by Chee et al, as a means for limiting and controlling the distal/proximal movement of the stiffening

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member with respect to the cannula of the catheter in a manner known in the prior art (column 8, lines 3-13).

In regards to claim 16, in a modified catheter of Miraki, Goodin, Lombardo, and Chee et al, Miraki teaches that the distal end of the stiffening member [12] comprises a retaining portion (retaining rings [148][150]) having an exterior cross-sectional area that is greater than the interior cross-sectional area of the passageway of the cannula [146] (Figure 7) so as to prevent the distal end the stiffening member from passing through the passageway of the cannula (column 9, lines 36-43).

In regards to claim 17, in a modified catheter of Miraki, Goodin, Lombardo, and Chee et al, Miraki teaches that the retaining portion (retaining rings [148][150]) comprises rings affixed to the distal end of the stiffening member [12], the rings having an outer diameter that is greater than the inside diameter of the cannula [146]. As required by claim 17, Miraki does not teach that the retaining portion is a rounded bead, as Miraki teaches rings. At the time the invention was made, it would have been an obvious matter of design choice to a person having ordinary skill in the art to shape the retaining rings of Miraki as rounded beads because Applicant has not disclosed that a rounded bead, as compared to a ring, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with retaining rings as opposed to a retaining bead because both retaining structures perform the same function of preventing the stiffening member from completely passing through the cannula. Therefore, it would have been an obvious matter of design choice to modify Miraki to obtain the invention as specified in claim 17.

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki and Goodin, as applied to claim 19 above, and further in view of Hernandez et al (US 5,269,759).

In regards to claim 20, in a modified catheter of Miraki and Goodin, Miraki teaches that the connector [118] comprises a female luer fitting [122] (Figure 5); however, Miraki is silent about whether the inflation device that is connected to the fitting is a syringe. As illustrated by Hernandez et al, it is common practice in the art to administer fluid via a syringe: Hernandez et al teaches a balloon catheter [14] (Figure 1) onto which a syringe is connected at a side port [17], having a luer fitting, in order to force inflation fluid under pressure to inflate the balloon [16] of the catheter (column 5, lines 45-52). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the syringe, as taught by Hernandez et al, as the inflation device to inflate the balloon, of the modified catheter of Miraki and Goodin, as the syringe will allow inflation fluid to be forced under pressure to inflate the balloon (column 5, lines 45-52).

14. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki and Goodin, as applied to claim 23 above, and further in view of Swanson (US 5,605,543).

In regards to claim 24, in a modified catheter of Miraki and Goodin, Miraki is silent about whether the first physical property of the stiffening member is a first stiffness and the second physical property of the stiffening member is a second stiffness, the first

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stiffness being greater than the second stiffness. Swanson teaches a balloon catheter [10] (Figure 1) with a guidewire tube [20] composed of a proximal guidewire tube [21] and a distal guidewire tube [22], with the proximal guidewire tube being stiffer than the distal guidewire tube (column 4, lines 43-52). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the varying stiffness properties of the stiffening member, as taught by Swanson, to the two portions of the stiffening member, of the modified catheter of Miraki and Goodin, in order to enhance pushability of the resultant catheter since the proximal end is stiffer than the distal end (column 4, lines 53-55).

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
12/29/2008

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761